



Australian Government

Department of Health
Therapeutic Goods Administration

2018 GMP Forum

Tuesday, 26 June 2018

PROGRAM

Time	Topic	Speaker	Room
8:15am	Registration		Marble Foyer
8:30am	Welcome tea and coffee		
9:00am	Welcome and introductory remarks	Ben Noyen – Assistant Secretary, Manufacturing Quality Branch (MQB)	Grand Lodge
9:05am	Keynote address	Adjunct Professor John Skerritt – Deputy Secretary, Health Products Regulation Group (HPRG)	
9:25am	Overview of TGA's involvement in the International Regulatory Environment	Jenny Hantzinikolas – Director, Inspections Section (IS), MQB	
9:50am	TGA Fees & Charges	Ben Noyen	
10:10am	GMP Clearance updates - MRA and CV processes <ul style="list-style-type: none">- Changes- Improvements- Challenges	Stephen Farrell – Acting Director, GMP Clearance Section, MQB	
10.30am MORNING TEA Marble Foyer			
11:00am	Driving a GMP culture to provide supporting evidence of better business outcomes	Robert Counce – Senior GMP Inspector, IS	Grand Lodge
11:45am	Updating Manufacturing Principles: PIC/S GMP Guide PE009-13 implementation and future updates	Matt Davis - Senior GMP Inspector, IS	

Time	Topic	Speaker	Room
12.30pm LUNCH Marble Foyer or Doric Room			
CONCURRENT PRESENTATION SESSIONS			
1:30pm	Expectations with Adoption of the PIC/S GMP Guide PE009-13	Session Chair - Matt Davis	Grand Lodge
	- Chapter 1 & 2 - Pharmaceutical Quality System & Personnel: PQS Clarifications, QMR requirements and Supply Chain, Quality Policy, QA/QC added responsibilities, consultant requirements	Neale Baldwin - Team Leader & Senior GMP Inspector, IS	
2:00pm	- Annex 15 – Qualification and Validation	Robert Counce	
2:30pm	- Chapter 4 & 6 – Documentation & Quality Control: Retention of documents, expectations for instructions & records, clarification on required procedures, QC Trending of CQA's, clarification for reagents, reference standards, microbial reagents/media	Maurice Makdessi - Senior GMP Inspector, IS	
2:40pm	- Chapter 7 – Outsourced Activities: Detailed clarification/scope of outsourced activities	Emmett Broderick - GMP Inspector, IS	
2:50pm	- Annex 2 - Manufacture of biological medicinal substances and products for human use & Annex 11- Computerised systems: Biological Medicinal requirements. Computerised system clarifications	Francesco Cicirello – GMP Inspector, IS	

Time	Topic	Speaker	Room
3:05pm	- Questions	All	
1:30pm	GMP Obligations for Small and Medium Enterprises (SMEs)	Session Chair – Craig Davies - Director, Recalls Section, MQB	Ionic Room
	- Overview of the SME Assist program	Tahli Fenner – Acting Director, Regulatory Guidance and SME Support Section	
1:50pm	- Therapeutic Goods regulation and the GMP inspection process: An inspector's perspective	Greg Orders - Senior GMP Inspector, IS	
2:30pm	- Understanding your supply chain (GMP agreements for GMP Clearance)	Stephen Farrell Darika Sowana - Assistant Director, GMP Clearance Section, MQB	
3:10pm	- Recalls	Craig Davies	
3.30pm AFTERNOON TEA Marble Foyer or Doric Room			
CONCURRENT INTERACTIVE SESSIONS			
The following concurrent sessions are intended to be interactive. For each topic listed below, the nominated presenter will speak for 5-10 minutes and the remainder of each 25 minute topic will be available for delegate participation by way of commentary and Q&A.			
	GMP inspection requirements	Session Chair – Jenny Hantzinikolas / Neale Baldwin	Grand Lodge
4:00pm	- Risk based approach to inspection frequency, re-inspection frequency & different product types, including APIs	Doreene Kohalmi - Senior GMP Inspector, IS	
4:25pm	- Emerging trends & developments, common inspection deficiencies and other concerns	Jenny Hantzinikolas	
	SME Education	Session Chair – Craig Davies	Ionic Room
4:00pm	- GMP Clearance processes - common mistakes made with applications	Stephen Farrell	

Time	Topic	Speaker	Room
		Darika Sowana	
4:25pm	- Uniform Recall Procedure for Therapeutic Goods – application and case studies	Michael Wholley – Assistant Director, Recalls Section, MQB	
4:50pm	Concluding remarks	Ben Noyen	Grand Lodge
		Craig Davies	Ionic Room
5:00pm	Meeting close		
5:00 – 6:00 pm Complimentary drinks Marble Foyer			